

REMARKS

The Invention

The present invention is directed to compositions capable of inducing an immune response to cytotoxic T cell epitopes of a full length protein in a mammal. The composition comprises an amount of *Bacillus anthracis* anthrax protective antigen and a full length protein bound to an anthrax protective antigen binding protein sufficient to elicit a cytotoxic T lymphocyte immune response. The molar ratio of protective antigen to the full length protein bound to the anthrax protective antigen binding protein is greater than one and the anthrax protective antigen binding protein comprises at least the first 250 amino acid residues of the lethal factor of *Bacillus anthracis* and less than all of the amino acid residues of the lethal factor.

Status of the Claims

Claims 1-6 are pending in the application. After entry of this amendment, claim 1 has been amended to recite that the compositions comprising *Bacillus anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein are an amount sufficient to elicit a cytotoxic T lymphocyte (CTL) immune response. Support for this amendment can be found, in the specification on, *e.g.*, page 6, lines 22-24, which defines a unit dose as an "amount of the vaccine that is a safe and therapeutically effective amount, which produces the desired results, *e.g.*, an immune response"; and page 4, lines 5-6, which indicates that the compositions of the invention target the cell-mediated immune system. Additional support can be found in the specification starting at, *e.g.*, page 17, line 20 to page 19, which teaches how to assay CTL responses *in vitro* and *in vivo*. Thus, this amendment adds no new matter.

Rejection under 35 U.S.C. § 103

Claims 1-6 stand rejected as unpatentable over Leppla *et al.*, WO 94/18332 ("Leppla *et al.*"). In making the rejection in the Office Action mailed December 1, 2002, the

Examiner alleged that in view of the teachings of Leppla, it would have been obvious to optimize the composition to obtain the molar ratio recited in claim 1. The rejection further alleged that the intended use carries no patentable weight because the claimed product is the same as an optimized product of Leppla. To the extent that the rejection applies to the amended claims, Applicants respectfully traverse.

To establish a *prima facie* case of obviousness, (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. (See, M.P.E.P., § 2143, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As amended, the claims recite that compositions comprise *Bacillus anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein in an amount sufficient to elicit an immune response, *i.e.*, a CTL response.

Applicants respectfully assert that the presently claimed invention represents a separately patentable subgenus of the compositions described in Leppla *et al.* Leppla *et al.* generically disclose compositions comprising *B. anthracis* anthrax protective antigen and protein bound to an anthrax protective antigen binding protein. The present claims require that the compositions comprising *B. anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein be *an amount sufficient to induce a CTL response*. In contrast to the presently claimed invention, Leppla *et al.* does not teach or suggest that the compositions should be an amount sufficient to induce a CTL response. Thus, an element of the presently claimed invention is absent from the disclosure of Leppla *et al.*

Moreover, without the teachings of the instant application, *i.e.*, without impermissible hindsight, one of skill in the art would have no motivation to modify the disclosure of Leppla *et al.* to make the presently claimed compositions comprising *B. anthracis*

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anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein in an amount sufficient to induce a CTL response. Thus, the present invention is a selection invention directed to a separately patentable subgenus of compositions comprising *B. anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein.

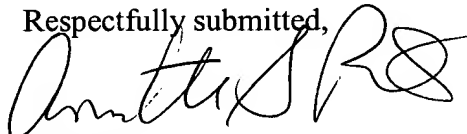
Since, *Leppla et al.* does not disclose all of the elements of the presently claimed invention and one of skill in the art would not have been motivated to modify the disclosure of *Leppla et al.*, Applicants respectfully submit that a *prima facie* case of obviousness has not been established. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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